IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff,

v.

ANTHONY G. BROWN, *et al.*,

Defendants.

No. 1:24-cv-01557-MJM

* * * * * * * * * * * *

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

ANTHONY BROWN, *et al.*,

Defendants.

No. 1:24-cv-01631-GLR

* * * * * * * * * * * *

ABBVIE INC, *et al.*,

Plaintiffs,

v.

ANTHONY G. BROWN, *et al.*,

Defendants.

No. 1:24-cv-01816-MJM

* * * * * * * * * * * *

ASTRAZENENCA PHARMACEUTICIALS LP,	*	
Plaintiff,	*	
v.	*	No. 1:24-cv-01868-MJM
ANTHONY BROWN, *et al*.,	*	
Defendants.	*	

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DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF ASTRAZENECA PHARACEUTICALS LP'S MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

The parties' dispute about the scope and effect of Maryland House Bill 1056 ("HB 1056") largely centers on a narrow legal issue—that is, whether HB 1056[1] regulates price, as AstraZeneca Pharmaceuticals LP ("Plaintiff" or "AstraZeneca") and other plaintiffs insist, or whether it regulates the delivery of 340B drugs purchased by covered entities.

For purposes of resolving that dispute and deciding whether HB 1056 survives AstraZeneca's facial attack,[2] the Court must base its determination on the actual text of HB 1056 and what circumstances or transactions the express terms of the statute purport to regulate, and not on what the parties argue the text states. Nor should the Court's focus be on circumstances that manufacturers contend may occur after covered entity-purchased drugs are delivered to pharmacies in accordance with HB 1056. *See* Complaint ("Compl."), ECF 1, ¶ 35 (alleging that the growth of contract pharmacy arrangements has "facilitated increased diversion and duplicate discounts"). Because it is beyond the scope of HB 1056, what may happen after the completion of a purchase and delivery of 340B drugs is not relevant to an assessment of the constitutionality of HB 1056.

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[1] HB 1056, now codified at in Section 12-6-09.1 of the Health Occupations Article of the Maryland Annotated Code, went into effect on July 1, 2024.

[2] To prevail on its facial challenge, Plaintiff must show that the law is unconstitutional in ***all*** of its application. *See United States v. Salerno*, 481 U.S. 739, 745 (1987) ("A facial challenge to a legislative Act is, of course, the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid.").

By its express terms, HB 1056 does not compel manufacturers to offer 340B drugs for sale to pharmacies, does not entitle pharmacies to purchase drugs at the discounted prices dictated by the 340B Program, and does not create a category of covered entities beyond the scope of the 340B Program. Because it only applies to purchases by covered entities, HB 1056 does not entitle any entity that is not a "covered entity," as determined by federal law, to purchase drugs at the prices set by federal law.

On the one hand, the focus of HB 1056 is on just one (delivery) of many possible provisions that may be contained in a manufacturer's offer for the sale of 340B drugs and any resulting purchase agreement. The 340B statute, of course, regulates another of those possible terms—price. *See* 42 U.S.C. § 256b(a)(1) (requiring that manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."). Any of the other of the multitude of possible terms of an agreement, such as payment terms (*e.g.*, cash or credit), limitation of liability, representations and warranties, and insurance requirements, are not regulated by 340B or HB 1056 and can be negotiated between manufacturers and covered entities unless and to the extent they are subject to other laws.

On the other hand, HB 1056 does not focus on or regulate what occurs after delivery of drugs purchased by a covered entity. Thus, for purposes of assessing the constitutionality of HB 1056, it is irrelevant to whom title may transfer after delivery of drugs purchased by a covered entity. Likewise, because HB 1056 does not regulate what occurs before the initiation of a purchase transaction (whether by the making of an offer by a manufacturer or placement of a purchase order by a covered entity), it is also irrelevant

if "340B discounts are requested for pharmacy sales that have already occurred." Plaintiff's Memorandum in Support of its Motion for a Preliminary Injunction, ECF 29-1 ("Pl. Mem."), at 3 (emphasis omitted). Rather, HB 1056 simply mandates that manufacturers comply with covered entities' instructions to deliver 340B drugs to "a pharmacy that is under contract with or otherwise authorized by a covered entity to receive 340B drugs on behalf of the covered entity." Md. Code Ann., Health Occ. § 12-6-09.1(c)(1).

If, after delivery, a covered entity transfers title of its 340B drugs to a pharmacy and if such transfer constitutes diversion in violation of the 340B statute, that is a matter for federal regulators as prescribed by federal law. *See* 42 U.S.C. §§ 256b(d)(3) (providing for ADR process), 256b(a)(5)(C) (providing HHS and manufacturers with audit rights); *see also Eli Lilly & Co. v. United States Dep't of Health & Hum. Servs.*, No. 1:21-cv-00081-SEB-MJD, 2021 WL 5039566, *20 n.14 (S.D. Ind. Oct. 29, 2021), *appeal docketed*, No. 21-3405 (7th Cir. Dec. 30, 2021) ("[T]here can be no dispute that Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal litigation."). Likewise, if a party's conduct before the placement of an order by a covered entity violates the 340B statute, that too is a matter for federal regulators. What occurs before the placement of an order for 340B drugs and after delivery is beyond the purview of HB 1056.

No matter how many times Plaintiff and its peers assert that HB 1056 regulates pricing does not make it true if the text of the statute states otherwise. An unvarnished reading of HB 1056 does not support Plaintiff's assertion here. Indeed, if Plaintiff wants

to choose not to sell drugs to pharmacies at any price (340B or otherwise), HB 1056 does not disturb that choice. However, under HB 1056, Plaintiff cannot choose to refuse to deliver "340B drugs" to pharmacies when instructed to do so by covered entities.

FACTUAL AND LEGAL BACKGROUND

Defendants incorporate, as if fully stated herein, the factual and legal background section set forth at pages 4 through 14 of defendants' memorandum of law in support of defendants' motion to dismiss and in opposition to plaintiff's motion for preliminary injunction filed in this Court in Pharmaceutical Research and Manufacturers of America v. Anthony Brown, Case No. 1:24-cv-01631-MJM (the "PhRMA Lawsuit"), ECF 19-1. Additionally, Defendants incorporate, as if fully stated herein, the relevant factual allegations in the complaint as summarized in Defendants' memorandum in support of their motion to dismiss filed in this case. *See* ECF 17-1, at 5-7.

STANDARD OF REVIEW

A preliminary injunction is "'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *Harrell v. University of Md. Sch. of Pharmacy*, No. MJM-24-104, 2024 WL 2155023, at *5 (D. Md. May 13, 2024) (quoting *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008)). The purpose of a preliminary injunction is to "protect the status quo and to prevent irreparable harm during the pendency of a lawsuit [and] ultimately to preserve the court's ability to render a meaningful judgment on the merits." *Moore v. Bishop*, No. JKB-17-1919, 2018 WL 2165299, at *5 (D. Md. May 10, 2018), *aff'd*, No. 18-6663, 2019 WL 93269 (4th Cir. Jan. 3, 2019) (citation omitted).

To obtain such relief, Plaintiffs must (1) establish that they are likely to succeed on the merits, (2) that they are likely to suffer irreparable harm in the absence of preliminary relief, (3) that the balance of equities tips in their favor, and (4) that an injunction is in the public interest. *Winter*, 555 U.S. at 20, 22. Thus, a moving party "must make a 'clear showing' of [the] four requirements" to obtain preliminary injunctive relief. *Harrell*, 2024 WL 2155023, at *5 (quoting *Low Tide Brewing, LLC v. Tideland Mgmt. LLC*, No. 2:21-CV-0775-DCN, 2021 WL 1381123, at *2 (D.S.C. Apr. 12, 2021)) (brackets in *Low Tide*).

ARGUMENT

I. PLAINTIFF IS NOT LIKELY TO SUCCEED ON THE MERITS OF ITS PREEMPTION CLAIMS TO INVALIDATE HB 1056.

Counts one and two of the complaint assert that HB 1056 is preempted by the 340 Program (Compl., ¶¶ 98-103) and by the federal patent laws (Compl., ¶¶ 104-107), respectively. To avoid further repetition of points and authorities expressed in the extensive briefing that has already occurred in these consolidated cases, and because Plaintiff's preemption allegations and arguments are substantially similar those made by the other plaintiffs, Defendants adopt and incorporate by reference the points and authorities set forth at: (1) pages 17 through 34 of Defendants' Memorandum of Law in Support of Defendants' Motion to Dismiss Complaint and in Opposition to Plaintiff's Motion for Preliminary Injunction (ECF 19-1) filed in the PhRMA Lawsuit; (2) pages 4 through 23 of Defendants' Memorandum of Law in Opposition to Plaintiff's Motion for Preliminary Injunction (ECF 26) filed in *Novartis Pharm. Corp. v. Brown*, Case No. 1:24-

cv-01557-MJM (the "Novartis Lawsuit");[3] (3) Defendants' Notice of Supplemental Authority (ECF 40) filed in the Novartis Lawsuit; (4) pages 5 through 12 of Defendants' Memorandum of Law in Opposition to Plaintiff's Motion for Preliminary Injunction (ECF 15) filed in *AbbVie, Inc. v. Brown*, Case No. 1:24-cv-01816-MJM (the "AbbVie Lawsuit"); and (5) pages 1 through 4 and 9 through 11 of Defendants' Memorandum of Law in Support of their Motion to Dismiss Plaintiff's Complaint (ECF 17-1) filed in this lawsuit.

In particular, Defendants rely on the decisions that rejected manufacturers' challenges to similar laws enacted by Arkansas and Mississippi and denied motions seeking to preliminarily enjoin those state's laws. *See Pharmaceutical Rsch. & Mfrs. of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024); *AbbVie Inc. v. Fitch*, No. 1:24-cv-184-HSO-BWR, 2024 WL 3503965 (S.D. Miss. July 22, 2024) ("*AbbVie-Fitch*"), appeal docketed, No. 24-60375 (5th Cir. July 24, 2024); *Pharmaceutical Rsch. & Mfrs. of Am. v. Fitch*, No. 1:24-cv-00160-HSO-BWR, 2024 WL 3277365 (S.D. Miss. July 1, 2024) ("*PhRMA-Fitch*"), appeal docketed, No. 24-60340 (5th Cir. July 5, 2024); *Novartis Pharms. Corp. v. Fitch*, ___ F. Supp. 3d ___, No. 1:24-cv-00164-HSO-BWR, 2024 WL 3276407 (S.D. Miss. July 1, 2024) ("*Novartis-Fitch*"), appeal docketed, No. 24-60342 (5th Cir. July 9, 2024).

[3] Defendants also adopt and incorporate by reference Exhibits A through E filed with ECF 26 in the Novartis Lawsuit. Specifically, those are the Affidavits of Sara K. Rich (Exhibit A), Sonya Bruton (Exhibit B), Patrick Mutch (Exhibit C), Kevin Lindamood (Exhibit D) and Matthew Perry (Exhibit E). Hereafter, references to "Exhibits" in this Memorandum are to these Affidavits.

Additionally, Plaintiff's reliance on the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), for the proposition that "no presumption against preemption of state law is appropriate here," is misplaced. Pl. Mem. at 11-12. In *Buckman*, individuals brought state-law tort claims based on injuries sustained from medical devices manufactured by the defendant. 531 U.S. at 346-47. The plaintiffs premised their state tort claims on a theory that the manufacturer made "fraudulent representations to the FDA as to the intended use" of its devices and, as a result, the devices were "given market clearance [by the FDA] and were subsequently used to the plaintiffs' detriment." *Id*. at 347.

In assessing whether the plaintiffs' "fraud-on-the-FDA" claims were preempted by federal law, the Supreme Court observed that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied' . . . such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Id.* (citation omitted). Thus, the Court held that the tort claims conflicted with, and were therefore preempted by, federal law because the "federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration."

In contrast with the statutory scheme at issue in *Buckman*, the 340B statute is silent regarding the subject matter of HB 1056, that is, delivery of drugs and, as decisions by the District of Columbia and Third Circuits confirm, federal regulators cannot enforce matters of delivery. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. United States Dep't Health & Hum. Servs.*, 58 F.4th 696 (3d Cir. 2023). And, unlike the field of policing fraud against federal agencies, states have traditionally

occupied the field of health and safety. Thus, in *McClain*, "[n]otwithstanding the supremacy of federal law," the Eighth Circuit appropriately applied the "'presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause.'" 95 F.4th at 1140 (quoting *Hillsborough County v. Automated Med. Lab'ys, Inc.*, 471 U.S. 707, 715 (1985)). Indeed, in *AbbVie-Fitch*, the district court observed that drug manufacturers should have "foreseen that states might enact policies favoring dispensation at contract pharmacies." 2024 WL 3503965, at *20; *see also id*. at *7 ("'[D]eference to our federalism counsels a presumption that areas of law traditionally reserved to the states . . . are not to be disturbed absent the clear and manifest purpose of Congress.'") (citation omitted; ellipses in *AbbVie-Fitch*). In accord with decisions by the Eighth Circuit and the Southern District of Mississippi, in assessing whether HB 1056 is preempted, this court too must apply the "strong presumption against preemption when the federal government regulates in areas traditionally left to the states, such as health and safety." *Pinney v. Nokia*, 402 F.3d 430, 457 (4th Cir. 2005).

Every court that has addressed the issue has confirmed that the 340B Program statute is silent as to both delivery itself and delivery terms of offers or contracts. In light of that statutory silence, the District of Columbia and Third Circuits held that HRSA and HHS are not authorized to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. *See Johnson*, 102 F.4th 452; *Sanofi Aventis*, 58 F.4th 696. And, applying a presumption against preemption, in light of that same statutory silence, the Eighth Circuit and the Southern District of Mississippi held that states may regulate

delivery of 340B drugs. *See McClain*, 95 F.4th at 1143-46;[4] *AbbVie Inc.-Fitch*, 2024 WL 3503965 at *8-16; *Novartis-Fitch*, 2024 WL 3276407 at *5-10; *PhRMA-Fitch*, 2024 WL 3277365 at *6-13.

Second, throughout its memorandum (*e.g.*, Pl. Mem. at 2, 6, 7, 14), Plaintiff refers to "contract pharmacy sales." It is unclear whether Plaintiffs' references to "contract pharmacy sales" are to (1) drug sales by manufacturers to pharmacies, which sales are beyond the scope of both HB 1056 and 340B, (2) sales to covered entities of drugs that are delivered to pharmacies, or (3) both. Because Plaintiff alleges that HB 1056 allows "contract pharmacies to demand steep discounts," "requires manufacturers to also make 340B discounts available . . . *outside* the 340B program," "creates a new, sixteenth category of covered entity," and "extends price caps to a category of sales—contract pharmacy sales," it would seem that "contract pharmacy sales," as that term is used by Plaintiff, would refer to manufacturers' sales to pharmacies. Compl., ¶¶ 5, 67 (emphasis in original), 76, 80.

[4] Plaintiff's musings about *McClain* miss the mark. *See* Pl. Mem. at 15. In *McClain*, the court concluded that the Arkansas delivery statute was not preempted by federal law. 95 F.4th at 1143-46. When it explained that "[p]harmacies do not purchase 340B drugs, and they do not receive the 340B price discounts," the court was simply stating the obvious. The 340B statute does not allow pharmacies to purchase 340B drugs or receive 340B price discounts. Likewise, the 340B statute only permits dispensation of 340B drugs to patients of covered entities. 42 U.S.C. § 256b(a)(5)(B). As such, until dispensation of 340B drugs to patients, a covered entity would presumably strive to retain title to such drugs; otherwise, it may run the risk of violating the 340B statute's prohibition of diversion, and the potential for penalties and removal from the 340B program. *See* 42 U.S.C. §§ 256b(a)(5)(D); 256b(d)(2). But, as noted above, whether title of purchased drugs improperly passes after delivery is a matter of federal regulation and beyond the scope of HB 1056.

If it is Plaintiff's contention that HB 1056 requires manufacturers to offer 340B-priced drugs to pharmacies, then such contention is plainly refuted by the text of HB 1056, which only applies to purchases of 340B drugs by covered entities or to purchases by covered entities that would have occurred but for a manufacturer's refusal to comply with covered entities' delivery instructions. *See* Health Occ. § 12-6C-09.1(a)(2), (4) (definitions of "covered entity" and "340B drug")

Yet, Plaintiff contradictorily acknowledges that "contract pharmacy sales occur in the name of the covered entity."[5] Pl. Mem. at 6. If it is Plaintiff's contention that purchases of 340B drugs by covered entities are the subject of HB 1056, then they are correct. HB 105 mandates that, in such transactions, manufacturers comply with covered entities' delivery instructions.

In light of Plaintiff's acknowledgement that HB 1056 does not mandate sales of 340B drugs to pharmacies, it appears that its complaints are actually limited to its assertions that covered entities do not maintain title to 340B drugs and contract pharmacies are "typically" not agents of covered entities. Pl. Mem. at 6. As discussed above, title transfers of 340B drugs after completed purchases by covered entities are not within the purview of

[5] If it is Plaintiff's position that all "contract pharmacy sales" are to covered entities, then such sales (which are wholly consistent with 340B) must result in transfers of title to covered entities. It would, therefore, be inconsistent for Plaintiff to assert, as it does, that HB 1056 forces it to transfer title of its drugs to pharmacies. *See* Compl., ¶¶ 115-117.

HB 1056, but rather fall within the scope of 340B. Thus, if a covered entity's post-purchase transfer of 340B drugs results in diversion, that is a matter for federal regulators.[6]

Next, Plaintiff's assertion that a covered entity might instruct a manufacturer to deliver purchased drugs to a pharmacy that is not its agent makes little sense. Because, by its terms, HB 1056 only applies to transactions involving pharmacies which have entered into contracts with pharmacies or which are authorized by covered entities to take delivery of their 340B drugs, Health Occ. § 12-6C-09.1(c)(1), for purposes of a facial challenge, it is irrelevant whether, as Plaintiff argues, that particular pharmacies may be independent contractors, and not agents of particular covered entities. Pl. Mem at 6. That said, if a covered entity instructs a manufacturer in writing to deliver its 340B drugs to a particular pharmacy, it would seem that the instruction itself would constitute authorization.

HB 1056 applies to purchases of 340B drugs by covered entities. *See* Health Occ. § 12-6C-09.1(a)(4). HB 1056 also applies to purchases of 340B drugs covered entities would have made but for manufacturers' delivery restrictions. *Id.* Plaintiff asserts that this latter aspect of HB 1056 interferes with the federal law's offer requirement because, according to Plaintiff, federal law regulates all aspects and all possible provisions of a manufacturer's offer. *See* Pl. Mem. at 17. However, Plaintiff's assertion is unsupported

[6] Without conceding whether the replenishment model promotes or causes diversion of 340B drugs in violation of federal law or its relevance, even if the replenishment model causes HB 1056 to interfere with federal law, Plaintiffs concede that not all contract pharmacy sales involve application of the replenishment model. See Pl. Mem. at 6 (describing what Plaintiff contends "usually" occurs). Thus, for purposes of Plaintiff's facial challenge, it must be assumed that the replenishment model is not applicable to all covered entities' purchases of 340B drugs.

by (1) the text of 340B statute, which is silent as to most terms, including delivery, that might ultimately be memorialized in a drug purchase agreement and (2) the District of Columbia Circuit's decision in *Johnson*, which narrowly held that 340B's silence regarding delivery left HRSA and HHS without authority to require manufacturers to deliver 340B drugs to an unlimited number of pharmacies. Indeed, that court did not even consider whether states are permitted to regulate contract terms, such as delivery, about which the 340B statute is silent. Thus, Plaintiff makes an unsupported leap from *Johnson*'s holding that "340B merely requires manufacturers to propose to sell covered drugs to covered entities at or below a specified monetary amount," 102 F.4th at 460, to Plaintiff's broad assertion that federal law controls all possible terms of a manufacturer's offer.[7] Regardless, as discussed above, to the extent otherwise permitted by applicable law, HB 1056 does not impinge on manufacturers' ability to include in their offers any of the multitude of other provisions that might be appropriate for a drug purchase agreement.

Moreover, because it only pertains to 340B drug sales to covered entities, HB 1056's reference to drugs that "would have been purchased but for" manufacturers' restrictions on delivery refers to drugs that would have been purchased by covered entities, and not by pharmacies. And because the 340B statute alone regulates prices to be charged to covered

[7] The limited scope of the 340B statute may best be indicated by the title given to 42 U.S.C § 256b: "Limitation on ***Prices*** of Drugs Purchased by Covered Entities." (emphasis added).

entities, there is no merit to Plaintiff's assertion that HB 1056 "forbids setting too high a price." Pl. Mem. at 17.

Plaintiff chides the State for not explaining "how HB 1056 can be considered a regulation of drug delivery." Pl. Mem. at 14. However, the better question is how can it not? AstraZeneca's policy is to limit delivery of 340B drugs purchased by covered entities "to a single contract pharmacy for each covered entity that lacked is own in-house pharmacy." Pl. Mem. at 7; Compl., at ¶ 39. For covered entities which own an in-house pharmacy, by inference, it is AstraZeneca's policy to deliver only to the in-house pharmacy and not to any additional contract pharmacies. Because AstraZeneca's highly restrictive policy violates HB 1056, enforcement of HB 1056 would free covered entities from such restrictions.

Plaintiff also chides Defendant for failing "to consider whether [HB 1056] . . . draws any distinction between 340B drugs and other drugs." Pl. Mem. at 15. This shows that Plaintiff does not understand the law over which it sues Defendants because HB 1056 draws no such distinction; HB 1056 only regulates purchases of drugs by covered entities which, as a matter of federal law, are entitled to purchase 340B drugs. In addition, because HB 1056 does not mandate that 340B price discounts be offered to pharmacies, it does not, as Plaintiff asserts, "saddle" manufacturers with "new obligations." Pl. Mem. at 18. Manufacturers already must deliver drugs that are purchased by covered entities. HB 1056 simply regulates where those deliveries must be directed.

HB 1056 does not mandate that manufacturers sell drugs at 340B discounted prices to any party in transactions that would violate the 340B Program, and does not entitle any

party, other than 340B covered entities, to purchase discounted drugs through the 340B Program. In fact, HB 1056 expresses that it shall not be construed to conflict with federal law. Health Occ. § 12-6C-09.1(b). Like the Arkansas statute at issue in *McClain*, HB 1056 simply deters drug manufacturers from interfering with covered entities' chosen means of dispensing and distributing drugs to their patients, and the penalties for noncompliance with HB 1056 are aimed at activity (drug distribution) that falls outside the purview of the 340B Program. In short, HB 1056 regulates drug distribution, not drug pricing.

Further, the State's regulation of delivery does not implicate any aspect of the offer required by the 340B statute. As courts unanimously have held, the 340B statute regulates price, not delivery. Because the 340B statute is silent as to delivery, it neither requires nor prohibits a delivery term in a manufacturer's offer or in contracts for the sale of 340B drugs. And it is this silence that permits state regulation of delivery. Accordingly, HB 1056 is not preempted by federal law.

II. PLAINTIFF WILL NOT SUFFER IRREPARABLE HARM FROM ENFORCEMENT OF HB 1056.

Not only did Plaintiff fail to show that that it is likely to succeed on the merits, but Plaintiff also fails to show that it can satisfy the remaining factors for the Court to grant the motion. Plaintiff argues that HB 1056 will cause it to suffer irreparable harm for several reasons: (1) it will be exposed to state regulation; (2) it is being compelled to transfer its private property; (3) it will be forced to comply with an unconstitutional law, and (4) it will suffer financial losses that it will be unable to recover. Pl. Mem. at 23-27.

As an initial matter, the Court should reject any assertion of irreparable harm based on Plaintiffs' delay in bringing this lawsuit. Governor Moore signed HB 1056 into law on May 16, 2024 and it went into effect on July 1, 2024. Plaintiff did not bring this lawsuit until June 27, 2024 and did not file its motion for a preliminary injunction until August 19, 2024. *See* ECF 1, ECF 29. The lack of urgency displayed by Plaintiff to seek injunctive relief in a timely fashion to ensure briefing concluded before the effective date of HB 1056 contradicts any suggestion that Plaintiff will, in fact, incur irreparable harm now that HB 1056 is in effect. *Cf. Perry v. Judd*, 471 F. App'x 219, 224-26 (4th Cir. 2012).

Furthermore, Plaintiff's argument that HB 1056 takes its private property, ECF 3-1, at 26-27, ignores the text and purpose of HB 1056. As fully outlined herein, HB 1056, which must be construed to be consistent with applicable federal law, Health Occ. § 12-6C-09.1(b), does not require drug manufacturers to sell drugs at 340B discounted prices to any party that is not entitled to receive such discounts. The 340B Program requires sales only to covered entities and HB 1056 does not change that.

This Court has found that cases involving a violation of the Supremacy Clause do not give rise to irreparable harm *per se*. *Association of Am. Publishers, Inc. v. Frosh*, 586 F. Supp. 3d 379, 394 (D. Md. 2022). Furthermore, the mere possibility of irreparable harm is insufficient to permit issuance of a preliminary injunction. *Di Biase v. SPX Corp.*, 872 F.3d 224, 230 (4th Cir. 2017) (quoting *Winter*, 555 U.S. at 22). Plaintiffs do not allege that they are currently subject to an enforcement action in Maryland, nor do they allege that they received notice of any such investigation into their business practices and conduct in this State.

Any harm that Plaintiffs would suffer from enforcement of HB 1056 is, today, purely speculative. There is a mechanism that exists for Plaintiffs to recover the costs incurred if the Court later concludes that HB 1056 is unconstitutional. To the extent any harm is calculable, Plaintiff, which is one of the largest biomedical companies by revenue in the world,[8] would be able to provide data on lost sales and revenue for the duration of this litigation if it abides by HB 1056, which runs parallel to federal law. Or, if Plaintiff choses to violate Maryland law, it could easily calculate the total fines it would be potentially reimbursed if HB 1056 is found unconstitutional.[9] Plaintiff, with good reason, does not claim that it will suffer insolvency. *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994).

In contrast, a stay would wreak havoc on Maryland's qualified health centers, some of which have already closed because of the adverse financial impact of restrictions imposed by drug manufacturers on covered entities' use of contract pharmacies to dispense drugs purchased through the 340B Program. *See* Exhibit E, Affidavit of Matthew Perry.

[8] According to AstraZeneca's 2023 Annual Report, it enjoyed revenues of $45.8 billion and core operating profit of $14.5 billion last year. *See* AstraZeneca 2023 Annual Report, *available at* https://www.astrazeneca.com/investor-relations/annual-reports/annual-report-2023.html (last visited September 3, 2024).

[9] An action to recover these costs in this Court would be foreclosed by sovereign immunity. *See Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89 (1984) Without Defendants waiving any arguments, Plaintiffs could bring a claim in Maryland state court for the State constitutional violations, but not for the preemption and claims asserted under the Federal constitution. *See DiPino v. Davis*, 354 Md. 18, 50 (1999); *Widgeon v. Eastern Shore Hosp. Ctr.*, 300 Md. 520, 537-38 (1984).

These organizations provide meaningful and necessary medical and social resources to Maryland citizens who need the most support. *See* Exhibits A-E.

Plaintiff cannot satisfy the irreparable harm requirement on any of the causes of action in the complaint under which it seeks a preliminary injunction.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST WEIGH AGAINST GRANTING THE PRELIMINARY INJUNCTION.

"When a plaintiff seeks preliminary injunctive relief against the Government, the balance of the equities and the public interest factors merge." *Coreas v. Bounds*, 451 F. Supp. 3d 407, 429 (D. Md. 2020) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009) and *Roe v. Department of Def.*, 947 F.3d 207, 230 (4th Cir. 2020)). In arguing that the "balance of the equities and public interest favor granting relief to AstraZeneca," Pl. Mem. at 28, Plaintiff ignores the harm that covered entities will incur if the Court enjoins enforcement of HB 1056.

Meanwhile, because of pharmaceutical manufacturers' behavior, covered entities in Maryland have suffered and, without HB 1056, will continue to suffer financial harm which adversely impacts the availability of health care and affordable medications to populations they serve, many who live on incomes well below the federal poverty line. *See* Exhibits A-E. This inability to provide services to Maryland's indigent population creates catastrophic results. *Id.* For example, the financial impact of manufacturer restrictions on the use of contract pharmacies prevented the Family Health Centers of Baltimore ("FHCB") from providing dental and behavioral health services to the Brooklyn and Cherry Hill neighborhoods of Baltimore in 2023; and, ultimately, in 2023 FHCB had to

close for financial reasons, in part, due to reduced revenues that it generated from the 340B program. *See* Exhibit E. Other Maryland covered entities, including Choptank Community Health System and CCI Health Services have incurred, or expect to incur, losses in the millions of dollars due to manufacturer-imposed restrictions on their use of contract pharmacies. *See* Exhibits A and B. The loss of those dollars translates directly to adverse impacts on the availability of health care in disadvantaged communities. *Id*.

In passing HB 1056, the General Assembly did not limit manufacturers' ability to limit covered entities' use of multiple contract pharmacies in other states. "Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citation omitted). Courts should "pay particular regard for the public consequences in employing the extraordinary remedy of injunction," *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982), and there is danger to the public in precluding Maryland from being able to enforce HB 1056. *See Person v. Mayor & City Council of Balt.*, 437 F. Supp. 2d 476, 479 (D. Md. 2006) (stating that there is a substantial danger of a mistake in granting a preliminary injunction because the decision is made on an incomplete record).

The ultimate indignity is that Marylanders will continue to suffer if the Court grants the preliminary injunction relief sought by Plaintiffs. In today's health care system, patients rely on pharmacies to provide them with necessary pharmaceuticals. In seeking to put more money in its coffers by enjoining this law, just like manufacturers' failed attempts in arguing that the related Arkansas and Mississippi laws were unconstitutional,

AstraZeneca and other drug manufacturers seek to severely limit covered entities' ability to benefit from the 340B Program. This harms the public. The imposition of an injunction will not maintain the status quo because every day that manufacturers may impose restrictions on covered entities results in lost funding that covered entities can ill afford. *See* Exhibits A-E.

This factor, like all the others, favors the State. Thus, the Court should deny the motion for preliminary injunction.

CONCLUSION

The Court should deny Plaintiff's motion for preliminary injunction.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that, on this 3rd day of September, 2024 the foregoing was served by CM/ECF on all counsel of record.

/s/ Joshua Chazen
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